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TITLE: A Randomized Clinical Trial of Cognitive-Behavioral Treatment for PTSD in Women

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13. ABSTRACT (Maximum 200 Words)
This study is a randomized clinical trial comparing two types of individual psychotherapy for treating PTSD in 384 female veterans and active duty personnel at 11 sites. The treatments are a trauma-focused approach, Prolonged Exposure Therapy, and an approach focused on current needs and problems, Present Centered Therapy. Each site will enroll 32 patients over the 36 months of active recruitment in the study. The hypothesis is that Prolonged Exposure therapy will be more effective than Present Centered Therapy for the treatment of PTSD in female veterans and active duty personnel. The study has entered the randomized phase. There are no conclusions to date.

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INTRODUCTION

The study is a randomized clinical trial comparing two types of individual psychotherapy for treating Post Traumatic Stress Disorder (PTSD) in 384 female veterans and active duty personnel at 11 sites. This is a VA Cooperative Study. Walter Reed Army Medical Center is participating with ten (10) VA sites around the country. All data are compiled and analyzed at the VA Cooperative Studies Program Coordinating Center in Palo Alto, CA.

The treatments are a trauma-focused approach, Prolonged Exposure (PE) therapy, and an approach focused on current needs and problems, Present Centered Therapy (PCT). PE treatment consists of 10 weekly 90 minutes sessions. Procedures include education about common reactions to trauma, breathing retraining, prolonged (repeated) exposure to trauma memories, repeated in vivo exposure to situations the patient is avoiding due to trauma-related fear, and discussion of thoughts and feelings related to exposure exercises. The goal of PE is to reduce the individual's emotional response to the traumatic event or feared stimuli through habituation. PCT treatment follows the same 10 weekly 90 minutes session format. PCT is designed to provide emotional support for the trauma victim with emphasis on the individual's current life. The goal of treatment is to reduce distress and to increase a sense of mastery in day-to-day life.

Each site will enroll 32 patients over the 24 months of active recruitment in the study. The objective of the study is to evaluate the efficacy of prolonged exposure therapy for treating PTSD and associated problems in active duty and veteran women. The work will significantly expand knowledge about the treatment of PTSD in military women. The methodology for the study is summarized as follows: All participants, including self-referrals, will enter the study through referral by mental health clinicians. Following informed consent, participants will be screened for inclusion and exclusion criteria. If they meet these criteria and agree to participate, they will be randomly assigned to one of the two treatments, which will occur weekly for 10 weeks. Subjects will be assessed before treatment, immediately following treatment, and 3 and 6 months after the end of treatment.

The hypothesis is that PE will be more effective then PCT for treatment of PTSD in female veterans and active duty personnel. The primary outcome in this study is PTSD severity at the 3-month follow-up assessment as measured on the Clinician Administered PTSD Scale (CAPS).

BODY

There have been no published study findings to date. There have been 3 Addendums to this study since the last annual review. These are summarized below.

- Addendum 2, submitted 3 Mar 03, was approved by expedited review. This addendum modified the required number of training cases for the therapists. The number of training cases was changed from 2 cases to 1 case with Therapist Supervisor's approval.

- Addendum 3, submitted 10 June 03, was approved by expedited review. This addendum made "housecleaning" modifications to the Informed Consent and the Protocol e.g. minor typos, eliminating the MRMC volunteer data registry, which is not required

for this study, from the protocol Additionally, a new Release of Information form for consultation with referring therapists was approved. After consultation with Patient Administration and the Judge Advocate's office, they recommended not using the DD5006 but making a new one specific to the study.

- Addendum 4, submitted on 25 July 03, was approved by expedited review. This addendum addressed Human Subjects Research Review Board suggested changes to the HIPAA authorization and accompanying modifications to the Protocol.

A total of 130 study-wide participants were enrolled as therapist training cases as of 30 August 2003. As of September 2, 2003, there have been 119 study-wide participants randomized. Seven (7) of these randomized participants have completed all aspects of the study. Twenty two participants dropped out of the study or were dropped from the study for the following reasons: 1 was lost to follow-up, 1 completed study treatment but would not participate in follow-up assessments, 1 had serious suicidal or homicidal ideations, 1 dropped out because she was unhappy with the study treatment, 1 died (unrelated to the study intervention), 2 had logistical problems (i.e. child care) that prevented participation, 4 were unable to complete study treatment within the allotted 20 weeks, and 11 had other reasons for dropping out of the study after being randomized.

The number of subjects enrolled in the study at Walter Reed Army Medical Center (WRAMC) since last APR is 7 training cases and 2 randomized cases. The total enrolled to date at WRAMC is 9.

A total of five (5) subjects at the WRAMC site have withdrawn from the study. All had signed informed consents to be training case subjects. Three (3) of these subjects decided they no longer wanted to participate prior to beginning therapy. During assessments, one (1) subject disclosed involvement in a violent relationship, which is a study exclusion criterion. And one (1) subject did not complete the ten treatment sessions within the prescribed timeframe of 20 weeks.

Since the beginning of the clinical trial, study-wide there have been 12 Serious Adverse Events (SAE) and 1 Adverse Event (AE) among the 249 total (randomized and therapist training case) participants. Two of these events occurred at the WRAMC site: psychiatric hospitalization on July 15, 2002 of a participant entered into the study on June 18, 2003. This AE remains the only SAE or AE study-wide that has been determined to be study related (the patient reported that the therapy caused her to develop an exacerbation of her PTSD and related symptoms). Of the remaining 11 study-wide SAEs, 3 involved suicide attempts, 5 involved hospitalization for psychiatric reasons, 1 was a medical hospitalization, and 2 were deaths (one of a drug interaction confirmed by autopsy and one is being investigated as a homicide, neither of which were study-related). Thus far, the independent DSMB has not noted any association between the study intervention and SAEs and the rate of SAEs is generally low (12 SAEs among 249 participants).

KEY RESEARCH ACCOMPLISHMENTS

There have been no major research publications, presentations or other accomplishments to report at this time.

REPORTABLE OUTCOMES

Presentation:

Sheliga, Vivian; Engel, Charles; Gonzalez, Denise; Woodard, Pamela. Special Care for Special Women. A PTSD Treatment Trial For Women: Challenges and Lessons Learned. Sixth Annual Force Health Protection Conference, US Army Center for Health Promotion & Preventive Medicine. Albuquerque, New Mexico, August 2003 .

CONCLUSIONS

No conclusions are available at this time.